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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,373	09/08/2003	Joseph Page	262.1	8249
7590	08/29/2005		EXAMINER NATARAJAN, VIVEK	
Joseph Page PO Box 757 La Jolla, CA 92038			ART UNIT 3736	PAPER NUMBER
DATE MAILED: 08/29/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,373	PAGE ET AL.	
	Examiner	Art Unit	
	Vivek Natarajan	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/8/03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claim Objections

Claims 2 and 18 are objected to because of the following informalities: the term "whereby" should be replaced by "wherein" in order to set forth a positive limitation. Appropriate correction is required.

Claim 3 is objected to because of the following informalities: the word "contain" should be replaced by "containing". Appropriate correction is required.

Claim 8 is objected to because of the following informalities: the word "forms" appears to be missing from the phrase "arrangement of transducers __ a plurality". Appropriate correction is required.

Claim 10 is objected to because of the following informalities: the close parenthesis should be removed after the number 8. Appropriate correction is required.

Claim 12 is objected to because of the following informalities: the term "said" should be inserted before "detector". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 11-12, and 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Regarding Claim 9, it is unclear what elements or terms provide the basis for the phrase "either of said transducers".

Regarding Claim 11, the limitation "each ring" has insufficient antecedent basis. Additionally, Claim 11 indicates that the ring is bifurcated into a plurality of sub-elements. By definition, a bifurcation is a division of a whole into two parts. The ring can therefore not be "bifurcated" into more than two sub-elements, as the claim appears to require.

Regarding Claim 12, it is unclear what elements or terms provide the basis for the phrase "either of said sub-elements".

Regarding Claims 14-17, the phrase "is done" fails to set forth positive method limitations for the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Caro (US Patent No. 5,348,002).

Regarding Claim 1, Caro discloses an apparatus for determining the concentration of species in a biological substance comprising an illumination source and transducer means for detecting acoustic energy and generating a representative

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acoustic signal (see Figure 11 and the description thereof in col.20, lines 16-47).

Furthermore, in Figure 12, Caro shows a particular embodiment of this transducer consisting of an annular element 108 and a conical element 206, which is placed directly against the tissue 104. Caro teaches that the conical element concentrates the acoustic signal as it propagates along the cone shape towards element 108 (col.20, lines 48-60). Thus, a point located within the circular boundary of the interface between the tissue and the conical element is more strongly coupled to the detector than an immediately surrounding point located outside this boundary.

Regarding Claim 2, Caro teaches that the aforementioned conical element allows for concentration of the acoustic signal as it propagates from the tissue-detector interface to the acoustic transducer. The conical sub-element of the detector thus serves as a directional microphone, enhancing the acoustic signal generated in that portion of the tissue which lies within the tissue-detector interface boundary.

Regarding Claim 3, Caro discloses that the apparatus is arranged to address body tissue such as the earlobe, nose, or skin fold (col.8, lines 64-65), which all contain interstitial fluids.

Regarding Claim 4, Caro discloses that the apparatus may be applied to a determination of the composition of blood (col.8, lines 58-59).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro as applied to Claims 1-4 above, and further in view of Kruger (US Patent No. 5,713,356, which will herein be referred to as Kruger '356). Caro discloses the claimed apparatus except that the detector is comprised of a plurality of transducers arranged to form an axially symmetric annulus pattern including an optical port at the center.

Regarding Claim 5, Kruger '356 discloses a multi-element detector array 52 (Figure 11b) formed by a plurality of transducers.

Regarding Claim 6, Kruger '356 indicates that the transducers are arranged in an axially symmetric pattern.

Regarding Claim 7, Kruger '356 further indicates that the transducer array "may be formulated from a monolithic, annular array of...elements" (col.10, lines 45-47).

Regarding Claim 8, Kruger '356 shows in Figure 10 the transducers arranged in a plurality of concentric annuli.

Regarding Claim 10, Caro discloses that the transducer "is manufactured in the form of an annulus through which the illuminating light may pass" (col.20, lines 22-24). Kruger '356 shows in Figure 13 an embodiment of his invention in which the light source 20 is at the center of the annular array of transducers.

It would be obvious to one having ordinary skill in the art at the invention was made to modify the apparatus of Caro by utilizing a multi-element annular detector array as disclosed by Kruger '356 since this allows for phase delays to be effected later into

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the signals outputted by the transducers, and to include an optical port at the center of this array since Caro discloses that his apparatus may be implemented with illumination through an annulus-shaped transducer and Kruger '356 teaches one such arrangement.

Regarding Claims 9 and 11, the term "means of" does not constitute means-plus-function language. As a result, the examiner has not applied 35 U.S.C. 112, Par. 6 to these claims in considering possible prior art references.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caro and Kruger '356 as applied to claims 5-8 above, and further in view of Kruger (US Patent No. 6,104,942, herein referred to as Kruger '942). The combination discloses the claimed invention where the transducer is electrically coupled to a preamplifier but does not include an electronic means of effecting a phase delay of signals generated in the transducers. Kruger '942 discloses a phase adjustment circuit within an amplifier connected to the output of the transducer to allow the phase of the signal generated by the acoustic transducer to be modulated (col.7, lines 54-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the combination of Caro and Kruger '356 to include in the amplifier a circuit means to control the phase output of the transducer signals as taught by Kruger '942 since this allows for a phase delay to be effected in the signals generated by the transducer.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caro and Kruger '356 as applied to claims 5-8 above, and further in view of Beck et al. (US Patent No. 6,791,242). The combination discloses the claimed

invention except that the rings are divided into wedge-shaped sub-elements. Beck depicts in Figure 6 a wedge-shaped acoustic transducer 90. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the combination of Caro and Kruger '356 by using the aforementioned wedge-shaped transducers of Beck et al. since this shape allows for easy incorporation of the individual transducer sub-elements into the annular transducer array.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caro, Kruger '356, and Beck et al. as applied to Claim 11 above, and further in view of Kruger '942. The combination discloses the claimed invention where the transducer is electrically coupled to a preamplifier but does not include an electronic means of effecting a phase delay of signals generated in the transducers. Kruger '942 discloses a phase adjustment circuit within an amplifier connected to the output of the transducer to allow the phase of the signal generated by the acoustic transducer to be modulated (col.7, lines 54-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of the combination of Caro, Kruger '356, and Beck to include in the amplifier a circuit means to control the phase output of each wedge-shaped transducer sub-element as taught by Kruger '942 since this allows for a phase delay to be effected in the signals generated by any particular sub-element.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro in view of Lilienfeld-Toal (US Patent No. 6,484,044). Caro discloses a method of

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determining blood glucose concentration comprising the steps of illuminating a tissue sample in a fingertip with light, receiving pressure waves from illuminated tissue at a skin-surface interface, and converting the pressure waves into electronic signals at a conical transducer that is coupled more strongly to a point within the boundary of the detector-tissue interface than surrounding points outside this boundary. While Caro does not specifically refer to mid-infrared light, he does indicate that the illuminating light "typically has a frequency in the optical range" (col.7, lines 36-38). Lilienfeld-Toal teaches that the middle infrared region of the absorption spectrum for substances of interest contains fairly narrow absorption lines specific to each substance, such that using middle infrared light is preferable in illuminating the tissue sample for photoacoustic detection of blood analyte concentrations (col.2, lines 12-26). It would have been obvious to one having ordinary skill in the art at the time the invention was made to implement the photoacoustic method detailed by Caro with middle infrared light as taught by Lilienfeld-Toal since this allows for more accurate determination of biochemical concentrations.

Claims 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caro and Lilienfeld-Toal as applied to Claim 13 above, and further in view of Kruger '942. Caro in view of Lilienfeld-Toal discloses the claimed method except for the simultaneous conversion of pressure waves into signals at a plurality of locations, after which a phase delay is created electronically and introduced into at least one of the signals.

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Regarding Claim 14, Kruger '942 discloses a method of using a plurality of evenly spaced acoustic transducers (col.4, lines 49-51) to convert pressure waves into electronic signals.

Regarding Claim 15, Kruger '942 indicates that the outputs of the individual transducers are produced simultaneously and fed to a programmable delay circuit for introducing phase delays into those signals. Kruger '942 teaches that by altering the transducer delays, the focus point of the transducer can be moved to desired positions in the tissue (col.4, lines 53-62).

Regarding Claim 16, Kruger '942 discloses that the plurality of transducers are arranged evenly over a spherical surface, so that they are distributed about a symmetry axis.

Regarding Claim 17, Kruger '942 discloses a programmable delay circuit as it pertains to the plurality of transducers arranged evenly about a symmetrical spherical surface.

It would be obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by the combination of Caro and Lilienfeld-Toal to use multiple, symmetrically distributed transducers as taught by Kruger '942 since this allows for enhanced coupling of the detector to the tissue, and to include a step in which phase delays are effected into the signals outputted by a plurality of spatially removed acoustic transducers as taught by Kruger '942 since this allows control of the effective focal point of the detector.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Caro and Lilienfeld-Toal as applied to Claim 13 above, and further in view of Autrey et al. (US Patent No. 6,870,626). The combination discloses the claimed method except for reflecting the pressure waves from a shaped reflection surface to further propagate them to a focus. Autrey discloses a photoacoustic spectroscopy system in which the resultant acoustic waves from a sample are reflected via an acoustic reflector 64 to a detector 48 (Figure 12a). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method disclosed by the combination of Caro and Lilienfeld-Toal to include an intermediate step in which the pressure waves are reflected by a reflection surface so that the waves propagate to a focus on the detector as taught by Autrey since this enhances coupling of the detector to a target point on the tissue.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vivek Natarajan whose telephone number is (571)272-6249. The examiner can normally be reached on Mon-Fri, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on (571)272-4740. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

VN



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PRIMARY EXAMINER